IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA,	)	
Plaintiff,	)	
v.	)	Civil Action No. 19 C 3382
PHARMEDIUM SERVICES, LLC, a limited liability company, and SCOTT ALADEEN and WARREN HORTON, individuals,	)	
Defendants.	)	

COMPLAINT FOR PERMANENT INJUNCTION

The United States of America, Plaintiff, by and through its undersigned counsel, and on behalf of the United States Food and Drug Administration ("FDA"), respectfully represents as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), and this Court's inherent equitable authority, to permanently enjoin the defendants, PharMedium Services, LLC ("PharMEDium"), a limited liability company, and Scott Aladeen and Warren Horton, individuals (collectively, "Defendants") from: (a) violating 21 U.S.C. § 331(a) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce, articles of drug that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A) and/or 351(a)(2)(B) and/or that are misbranded within the meaning of 21 U.S.C. § 352(f)(1); (b) violating 21 U.S.C. § 331(k) by causing articles of drug to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A) and/or 351(a)(2)(B) and/or to become misbranded within the meaning of 21 U.S.C. § 352(f)(1), while such drugs are held for sale after shipment of one or more of their

components in interstate commerce; and (c) violating 21 U.S.C. § 331(d) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce, new drugs, as defined by 21 U.S.C. § 321(p), that are neither approved under 21 U.S.C. § 355, nor exempt from approval.

Jurisdiction and Venue

2. This Court has jurisdiction over the subject matter and all parties to this action under 28 U.S.C. §§ 1331, 1337, and 1345, and 21 U.S.C. § 332(a).

3. Venue in this district is proper under 28 U.S.C. § 1391(b) and (c).

Defendants and Their Operations

4. PharMEDium is a limited liability company formed in Delaware with its headquarters located at 150 North Field Drive, Suite 350, Lake Forest, Illinois 60045 ("PharMEDium Corporate Headquarters"), within the jurisdiction of this Court.

5. PharMEDium has four facilities registered under 21 U.S.C. § 353b as outsourcing facilities, which are located at: (1) 6100 Global Drive, Memphis, Tennessee 38141 ("Tennessee Facility"); (2) 913 North Davis Avenue, Cleveland, Mississippi 38732 ("Mississippi Facility"); (3) 12620 West Airport Boulevard, Suite 130, Sugar Land, Texas 77478 ("Texas Facility"); and (4) 36 Stults Road, Dayton, New Jersey 08810 ("New Jersey Facility"). PharMEDium most recently re-registered all four facilities as outsourcing facilities with FDA on November 12, 2018.

6. Scott Aladeen has been PharMEDium's President since January 28, 2019. Defendant Aladeen is the person most responsible for PharMEDium's operations. Defendant Aladeen has the authority to prevent, detect, and correct violations. He performs his duties at PharMEDium Corporate Headquarters, within the jurisdiction of this Court.

7. Warren Horton has been PharMEDium's Vice President for Quality and Research & Development since April 15, 2019. Defendant Horton is the most senior quality official at PharMEDium and is responsible for establishing and maintaining the quality operations at all facilities. He shares the authority to prevent, detect, and correct violations. Defendant Horton performs his duties at PharMEDium Corporate Headquarters, within the jurisdiction of this Court.

8. During their regular course of business, Defendants manufacture, process, pack, label, hold, and distribute articles of drug, within the meaning of 21 U.S.C. § 321(g)(1). Defendants' drugs are intended for injection and, by virtue of their labeling and/or route of administration, purport to be or are expected to be sterile. Sterile drugs are drugs that are required to be sterile under Federal or state law or drugs that, by nature of their intended use or method of administration, are expected to be sterile ("sterile drugs"). *See* 21 U.S.C. § 353b(d)(5). Defendants' sterile injectable drugs include, but are not limited to: oxytocin (uterotonic/labor inducer); hydromorphone, fentanyl citrate, and morphine sulfate (narcotic analgesics); magnesium sulfate and potassium chloride (electrolyte solutions); bupivacaine and ropivacaine (anesthetics); and atropine sulfate (anticholinergic/involuntary nervous system blocker).

9. Defendants mix commercially-available sterile drugs with a sterile diluent in syringes, intravenous bags, or cassette reservoirs.

10. Defendants' facilities contain "cleanrooms" where the production of purportedly sterile drugs occurs. The cleanrooms contain "ISO 5" and "ISO 7" processing areas (referring to International Organization for Standardization classifications for cleanrooms). ISO 5 processing areas are critical zones that, by designation, have the highest level of cleanliness within a facility.

11. Defendants do not distribute to individual patients with prescriptions, but instead fill orders for drugs compounded for "office use," often referred to as "office stock" (i.e., drugs compounded and distributed to a hospital or other health care provider not pursuant to a patient-specific prescription).

12. Defendants distribute their drugs to hospitals throughout the United States, including hydromorphone to New York, potassium chloride to Georgia, ropivacaine to Kentucky, and fentanyl citrate/bupivacaine to Montana.

13. Defendants manufacture drugs using components that were shipped in interstate commerce, including components from Pennsylvania and Illinois.

14. During their regular course of business, Defendants distributed drugs including, oxytocin, hydromorphone, fentanyl citrate, morphine sulfate, magnesium sulfate, potassium chloride, ropivacaine, and bupivacaine with labels that omitted the date that the drug was compounded, and labels and containers that failed to contain a list of active and inactive ingredients and the quantity or proportion of each ingredient.

The Act's Requirements

15. Under the Act, a "drug" includes any article that is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," 21 U.S.C. § 321(g)(1)(B), or that is "intended to affect the structure or any function of the body." 21 U.S.C. § 321(g)(1)(C).

16. A drug is deemed to be adulterated "if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health." 21 U.S.C. § 351(a)(2)(A).

17. The Act requires that drugs be manufactured in accordance with current good manufacturing practice ("CGMP"). 21 U.S.C. § 351(a)(2)(B); *see* 21 C.F.R. § 210.1(b). A drug

is deemed to be adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with CGMP to assure that it meets the requirements of the Act as to safety and that it has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess, regardless of whether the drug is actually defective in some way. FDA has promulgated CGMP regulations for drugs at 21 C.F.R. Parts 210 and 211.

18. A drug is deemed to be misbranded "unless its labeling bears adequate directions for use." 21 U.S.C. § 352(f)(1).

19. The Act requires, subject to certain exceptions not applicable here, that drug sponsors obtain FDA approval of a new drug application ("NDA"), an abbreviated new drug application ("ANDA"), or an investigational new drug exception ("IND") with respect to any new drug that is introduced into interstate commerce. 21 U.S.C. §§ 331(d), 355(a). A "new drug" includes "[a]ny drug . . . the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 321(p)(1).

20. To be eligible for the exemptions applicable to outsourcing facilities described in paragraph 23 below, the label of a drug compounded in an outsourcing facility must contain several specified statements and information, including the date the drug was compounded, 21 U.S.C. § 353b(a)(10)(A)(iii)(V), and a list of active and inactive ingredients that are identified by established name and the quantity or proportion of each ingredient, 21 U.S.C. § 353b(a)(10)(A)(iii)(X). If there is insufficient space on a drug label for a list of active and

inactive ingredients and the quantity or proportion of each ingredient, an outsourcing facility may include this information on the drug container. 21 U.S.C. § 353b(a)(10)(B)(i).

The Act's Exemptions for Drugs Compounded by an Outsourcing Facility

21. Compounding generally refers to the practice in which a licensed pharmacist or physician (or, in the case of an "outsourcing facility," a person under the direct supervision of a licensed pharmacist) combines, mixes, or alters ingredients to create a drug. Such drugs generally are tailored to the needs of identified individual patients, although outsourcing facilities are not required to obtain prescriptions for identified individual patients. *See* 21 U.S.C. § 353b(d)(4)(C).

22. Under the Act, an "outsourcing facility" is a facility that engages in the compounding of sterile drugs, registers as an outsourcing facility pursuant to 21 U.S.C. § 353b(b) and complies with all of the requirements of 21 U.S.C. § 353b. *See* 21 U.S.C. § 353b(d)(4)(A).

23. Under the Act, drug products compounded in a registered outsourcing facility are exempt from the Act's adequate directions for use and premarket approval requirements if the drugs compounded by the outsourcing facility are compounded in accordance with all of the conditions in 21 U.S.C. § 353b. *See* 21 U.S.C. § 353b(a).

24. Outsourcing facilities under 21 U.S.C. § 353b are not exempt from complying with CGMP. *See* 21 U.S.C. § 353b(a).

FDA's Recent Inspections of PharMEDium's Facilities

25. In 2017–2018, FDA conducted inspections at PharMEDium Corporate Headquarters and its outsourcing facilities, as a follow-up to a November 2016 regulatory meeting.

26. FDA investigators observed and documented numerous insanitary conditions, as described in paragraph 29 below, and deviations from CGMP requirements for drugs, as described in paragraph 33 below.

27. As discussed in paragraphs 38 and 43 below, FDA also observed and documented that Defendants manufactured and introduced into interstate commerce drugs with labeling that omitted information required by 21 U.S.C. § 353b(a)(10).

28. At the close of the 2017–2018 inspections, FDA investigators issued Forms FDA-483, List of Inspectional Observations ("Forms FDA 483") to PharMEDium representatives.

Adulteration Due to Insanitary Conditions

29. The insanitary conditions observed at PharMEDium during FDA's 2017–2018 inspections establish that drugs manufactured and distributed by Defendants are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A). The insanitary conditions documented by FDA include, but are not limited to, the following:

a. Defendants repeatedly recovered various types of microorganisms, including spore-forming bacteria and fungi, in the ISO 5 aseptic processing areas. For example, at the Tennessee Facility, an environmental monitoring sample revealed four colony-forming units of *Penicillium chrysogenum*, a spore-forming fungus, in an ISO 5 hood in which employees had processed at least 500 units of atropine sulfate. Similarly, personnel monitoring at the Tennessee Facility revealed seven colony-forming units of *Bacillus thuringiensis*, a spore-forming bacterium, on glove fingertips of an employee who had processed at least seventy units of bupivacaine. The Tennessee Facility distributed the atropine sulfate and bupivacaine and did not recall these drugs after determining that microorganisms were present during processing. The Mississippi and New Jersey Facilities also identified microorganisms on glove-fingertip

samples. The Texas Facility detected microorganisms in ISO 5 areas in over 200 environmental samples;

b. Defendants engaged in inadequate aseptic practices while processing purportedly sterile drugs. For example, FDA investigators observed an employee at the Mississippi Facility touch items in the trash container and then return to the ISO 5 processing area without first sanitizing or changing gloves;

c. Defendants detected microbial growth during media-fill runs at the Tennessee, Mississippi, Texas, and New Jersey Facilities;

d. Defendants failed to appropriately monitor their ISO 5 hoods for non-viable particles under dynamic (i.e., operational) conditions at the Tennessee, Mississippi, Texas, and New Jersey Facilities; and

e. Defendants failed to maintain the physical structure and equipment in ISO 5 processing areas. For example, FDA investigators observed a gap around a light fixture in an ISO 5 hood in the Tennessee Facility and chipped paint on the floor of a cleanroom at the Mississippi Facility.

30. The insanitary conditions that FDA investigators observed at Defendants' facilities during the 2017–2018 inspections establishes that drugs manufactured and distributed by Defendants are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A), in that they were prepared, packed, or held under insanitary conditions whereby they may have been contaminated with filth or whereby they may have been rendered injurious to health.

31. Defendants violate 21 U.S.C. § 331(a) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce, articles of drug that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A).

32. Defendants violate 21 U.S.C. § 331(k) by causing articles of drug to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A), while such drugs are held for sale after shipment of one or more of their components in interstate commerce.

Adulteration Due to Deviations from CGMP

33. During the 2017–2018 inspections, FDA investigators documented numerous deviations from CGMP that include, but are not limited to, the following:

a. Defendants failed to establish an adequate quality control unit that has the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and has the authority to investigate any errors that may have occurred, *see* 21 C.F.R. § 211.22(a). For example, the quality control unit at the Tennessee Facility failed to verify sterility, endotoxin, or potency results in batch records before the quality unit released the drugs for distribution. The Texas Facility's quality control unit released, in error or without appropriate justification, drug products for distribution that had failed endotoxin testing. In addition, the quality control units at both facilities failed to conduct adequate investigations into the release of out-of-specification products;

b. Defendants failed to thoroughly review and investigate unexplained discrepancies or the failure of a batch to meet any of its specifications, whether or not the batch has already been distributed, *see* 21 C.F.R. § 211.192. For example, after receiving failed potency or endotoxin test results at the Tennessee and New Jersey Facilities, Defendants retested the products without justification and disregarded the original failing results. Additionally, Defendants failed to extend their investigations into out-of-specification results to other potentially affected product lots. Defendants also failed to identify a root cause for the failures

or to close investigations into failing results in a timely manner. For example, at the Mississippi Facility, Defendants failed to identify the most probable root cause for several failed media-fill runs, and investigations into the failures did not extend to drug products processed by the same technician. Similarly, the Texas Facility's investigations into sterility failures were incomplete in that Defendants failed to identify the contaminating microorganisms and failed to assess other lots that may have been affected.

c. Defendants failed to establish and follow appropriate written procedures that are designed to prevent microbiological contamination of drug products purporting to be sterile, *see* 21 C.F.R. § 211.113(b). Employees at the Tennessee, Mississippi, Texas, and New Jersey Facilities failed to follow PharMEDium's aseptic technique procedures and engaged in improper practices during aseptic processing;

d. Defendants failed to establish adequate control systems necessary to prevent contamination during aseptic processing, *see* 21 C.F.R. § 211.42(c)(10). For example, the Mississippi and Texas Facilities had leaks in high efficiency particulate air filters in their ISO 5 hoods, but failed to investigate whether the leaks affected drugs processed before the leaks were discovered and repaired; and

e. Defendants failed to ensure that a drug product meets applicable standards of strength at the time of use by bearing an expiration date determined by appropriate stability testing, *see* 21 C.F.R. § 211.137(a). Specifically, two products processed at the Tennessee Facility had an expiration date that exceeded the time frame supported by stability data.

34. These observations establish that Defendants' drugs are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), in that the methods used in, or the facilities or controls used for, their manufacturing, processing, packing, or holding do not comply with CGMP to

assure that they meet the requirements of the Act as to their safety and that they have the identity and strength, and meet the quality and purity characteristics, which they purport or are represented to possess.

35. Defendants violate 21 U.S.C. § 331(a) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce, articles of drug that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B).

36. Defendants also violate 21 U.S.C. § 331(k) by causing articles of drug to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), while such drugs are held for sale after shipment of one or more of their components in interstate commerce.

Unapproved New Drugs

37. Many of Defendants' drugs, including, but not limited to, oxytocin, hydromorphone, fentanyl citrate, morphine sulfate, magnesium sulfate, potassium chloride, ropivacaine, and bupivacaine, are not generally recognized as safe and effective because there are no published adequate and well-controlled clinical studies of those drugs upon which qualified experts could conclude that the drugs are safe and effective. Therefore, they are new drugs within the meaning of 21 U.S.C. § 321(p).

38. Drugs manufactured at an outsourcing facility in compliance with 21 U.S.C. § 353b are exempt from the new drug approval requirements under 21 U.S.C. § 355. 21 U.S.C. § 353b(a). To be entitled to that exemption, Defendants need to meet all of the statutory elements of 21 U.S.C. § 353b for each drug product. *See* 21 U.S.C. § 353b(a). At the time of the 2017–2018 inspections, the labels for many of Defendants' drugs, including but not limited to, oxytocin, hydromorphone, fentanyl citrate, morphine sulfate, magnesium sulfate, potassium chloride, ropivacaine, and bupivacaine, failed to include the date the drug was compounded, as

required by 21 U.S.C. § 353b(a)(10)(A)(iii)(V), and the labels and containers for these drugs failed to contain a list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient, as required by 21 U.S.C. § 353b(a)(10)(A)(iii)(X) and 21 U.S.C. § 353b(a)(10)(B)(i). Thus, these drug products, which are new drugs, are not exempt from the approval requirements. *See* 21 U.S.C. § 353b(a) and 353b(d)(4)(A).

39. Defendants' oxytocin, hydromorphone, fentanyl citrate, morphine sulfate, magnesium sulfate, potassium chloride, ropivacaine, and bupivacaine lack an approved NDA or ANDA, as required by 21 U.S.C. § 355, and are not otherwise exempt from approval under 21 U.S.C. § 355(i). Hence, these drug products are unapproved new drugs.

40. Defendants' distribution into interstate commerce of these unapproved new drugs violates 21 U.S.C. § 331(d).

Misbranding Due to Inadequate Directions for Use

41. Due to their toxicity or other potentiality for harmful effect, or the method of their use, or the collateral measures necessary to their use, Defendants' drugs are not safe for use except under the supervision of a practitioner licensed by law to administer such drugs. As such, Defendants' drugs are "prescription drugs" within the meaning of 21 U.S.C. § 353(b)(1)(A).

42. "Adequate directions for use" means directions under which a layperson "can use a drug safely and for the purposes for which it is intended." 21 C.F.R. § 201.5. A prescription drug, by definition, cannot bear adequate directions for use by a layperson because such drug must be administered under the supervision of a licensed practitioner. *See* 21 U.S.C. § 353(b)(1). FDA has established exemptions for certain drug products from the requirements that labeling bear adequate directions for use, but because Defendants' drug products are unapproved new

drugs, they do not satisfy the conditions for any of these exemptions. *See* 21 C.F.R. §§ 201.115, 201.100.

43. Because PharMEDium's facilities are registered with FDA as outsourcing facilities, PharMEDium is required to comply with all of the requirements of 21 U.S.C. § 353b to be able to avail itself of the exemptions in that section. Because the labels for Defendants' drugs, including but not limited to, oxytocin, hydromorphone, fentanyl citrate, morphine sulfate, magnesium sulfate, potassium chloride, ropivacaine, and bupivacaine failed to include the date the drug was compounded as required by 21 U.S.C. § 353b(a)(10)(A)(iii)(V), and the labels and containers for these drugs failed to contain a list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient, as required by 21 U.S.C. § 353b(a)(10)(A)(iii)(X) and 21 U.S.C. § 353b(a)(10)(B)(i), these drugs do not qualify for the exemption in 21 U.S.C. § 353b from the requirement for adequate directions for use in 21 U.S.C. § 352(f)(1) and are, thus, misbranded. *See* 21 U.S.C. § 353b(a), 353b(d)(4)(A).

44. Defendants violate 21 U.S.C. § 331(a) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce, articles of drug that are misbranded within the meaning of 21 U.S.C. § 352(f)(1), in that the labeling of the drugs fails to bear adequate directions for use, and the drugs are not exempt from the requirements of 21 U.S.C. § 352(f)(1).

45. Defendants violate 21 U.S.C. § 331(k) by causing articles of drug that are not exempt from the requirements of 21 U.S.C. § 352(f)(1) to become misbranded within the meaning of 21 U.S.C. § 352(f)(1), while such drugs are held for sale after shipment of one or more of their components in interstate commerce.

Prior Inspections and Warnings to Defendants

46. FDA has conducted multiple inspections at PharMEDium's Corporate Headquarters and outsourcing facilities. During past inspections, particularly those occurring in 2013 and 2015–2016, FDA observed many of the same or similar violations of the Act observed during the 2017–2018 inspections. For instance, since the inspections in 2013, FDA investigators have observed deficiencies in Defendants' non-viable particle monitoring and sterility, endotoxin, or potency testing. Additionally, since the 2015 inspections, FDA has documented that Defendants recovered microorganisms in ISO 5 processing areas, engaged in inadequate aseptic processes, failed to thoroughly review and investigate unexplained discrepancies or the failure of a batch to meet specifications, and distributed drugs with labels that failed to contain the date a drug was compounded and a list of active and inactive ingredients.

47. FDA issued Warning Letters to PharMEDium on April 13, 2007, and again on July 18, 2014. The July 18, 2014, Warning Letter notified PharMEDium that its drug products were adulterated because they were manufactured under insanitary conditions and in violation of CGMP.

48. FDA held regulatory meetings with PharMEDium on July 22, 2009, and November 18, 2016.

49. Despite repeated promises to correct deficiencies, PharMEDium's violations persisted, as evidenced by the conditions FDA investigators observed during the 2017–2018 inspections.

50. The United States believes that, unless restrained by the Court, Defendants will further violate 21 U.S.C. § 331(a), (k), and (d), in the manner alleged herein.

WHEREFORE, the United States of America respectfully requests that this Court:

I. Permanently restrain and enjoin Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, from manufacturing, processing, packing, holding, labeling, or distributing any article of drug at and/or from the Tennessee Facility, unless and until Defendants bring their manufacturing, processing, packing, holding, labeling, and distribution operations into compliance with the Act and its implementing regulations to the satisfaction of FDA;

II. Permanently restrain and enjoin under 21 U.S.C. § 332(a) Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, from directly or indirectly doing or causing the following acts:

A. Violating 21 U.S.C. § 331(a) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce, any drug that is adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A) and/or 351(a)(2)(B), and/or misbranded within the meaning of 21 U.S.C. § 352(f)(1);

B. Violating 21 U.S.C. § 331(k) by causing any drug to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A) and/or 351(a)(2)(B), and/or misbranded within the meaning of 21 U.S.C. § 352(f)(1), while such drug is held for sale after shipment of one or more of its components in interstate commerce; and

C. Violating 21 U.S.C. § 331(d) by introducing or causing the introduction into interstate commerce, or delivering or causing the delivery for introduction into interstate

commerce, of any new drug that is neither approved under 21 U.S.C. § 355, nor exempt from approval;

III. Authorize FDA pursuant to this injunction to inspect Defendants' places of business and all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any drug to ensure continuing compliance with the terms of the injunction, with the costs of such inspections, including testing and sampling, to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

IV. Award the United States costs and other such relief as the Court deems just and proper.

DATED this 20th day of May, 2019.

Respectfully submitted,

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